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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/043,289	01/14/2002	Mark J. Cooper	003659.83112	7434

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WASHINGTON, DC 20001

EXAMINER

KATCHEVES, KONSTANTINA T

ART UNIT	PAPER NUMBER
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1636

DATE MAILED: 02/25/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/043,289

Applicant(s)

COOPER, MARK J.

Examiner

Konstantina Katcheves

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 January 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-200 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) See Continuation Sheet is/are rejected.
- 7) ☒ Claim(s) See Continuation Sheet is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 14 January 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 4/26/2002.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Claims 1-200 are pending in the present application.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 3, 9, 47, 48, 49, 90, 99, 113, 123, 154, 157, 161, 163 and 200 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 3, 4 and 5 of U.S. Patent No. 6,339,065. Although the conflicting claims are not identical, they are not patentably distinct from each other because the examined claims are either

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anticipated by, or would have been obvious over, the reference claims. See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985).

Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 113, 123, 154, 157, 161, 163 and 200 are generic to all that is recited in claims 1, 3 and 5 of U.S. Patent No. 6,339,065. The instant claims a method comprising culturing a mammalian cell which comprises (1) a DNA molecule comprising a coding sequence for a mutant form of a papovavirus large T antigen (SV40) which contains a binding site for a papovavirus origin of replication (SV40) and which having a mutation in the p53 binding domain of the large T antigen and a mutation in a RB binding domain of the large T antigen; and (2) a first promoter which controls expression of the mutant papovavirus large T antigen; and (3) a first episome comprising a coding sequence for a protein and the papovavirus origin of replication. The method of US Patent No. 6,339,065 also comprises these elements however does not specifically recites the culturing step, but instead recites a transfection step. The transfection step is inherent in the presently claimed invention because it would necessarily be required in order to get the exogenous DNA into the cell. Therefore, the claims of US Patent 6,339,065 falls entirely within the scope of the present claims, or in other words, the present claims are anticipated the claims of US Patent 6,339,065. Claims 1, 3, 9, 47, 48, 49, 90, 99 recite a kit and mammalian cell for use with the method of claims 113, 123, 154, 157, 161, 163 and 200, which would have been inherent to the method of the claims of US Patent 6,339,065 and thus obvious to one of ordinary skill in the art.

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Claims 1, 2, 4, 6, 8, 10, 15, 49, 54, 56, 58, 60, 65, 90, 94, 96, 98, 100, 105, 113, 118, 120, 122, 124, 129, 154, 158, 160, 162, 164, 169, 199 and 200 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 2, 3, 4, 5, and 7 of U.S. Patent No. 5,624,820 ('820 Patent). Although the conflicting claims are not identical, they are not patentably distinct from each other because the examined claims are either anticipated by, or would have been obvious over, the reference claims. See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985).

Claims 113, 118, 120, 122, 124, 129, 154, 158, 160, 162, 164, 169 and 200 are generic to all that is recited in claims 1-5 and 7 of the '820 Patent. The instant claims a method comprising culturing a mammalian cell which comprises (1) a DNA molecule comprising a coding sequence for a mutant form of a papovavirus large T antigen (BK) which contains a binding site for a papovavirus origin of replication (BK) and which having a mutation in the p53 binding domain of the large T antigen and a mutation in a RB binding domain of the large T antigen; and (2) a first promoter which controls expression of the mutant papovavirus large T antigen; and (3) a first episome comprising a coding sequence for a protein and the papovavirus origin of replication.

The invention of the patent claims comprise a method of expressing a foreign gene in a mammalian cell comprising: (1) transfecting the mammalian cell with a replication-competent, transformation-negative vector comprising at least one papovavirus origin of replication, (2) a first DNA sequence encoding a mutant form of papovavirus large T antigen which contains a replication-competent binding site for said origin of replication and which is negative for binding

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to and to retinoblastoma tumor suppressor gene product due to a mutation in a codon in the p53 binding domain of said large T antigen and a mutation in a codon in the RB binding domain of said large T antigen (3) the DNA sequence being operatively linked to a first promoter which is functional in a mammalian cell, and (4) a second DNA sequence encoding the foreign gene operatively linked to a second promoter which is functional in the mammalian cell.

Although the patent claims do not recite “the first episome comprising a coding sequence for a protein,” the claims do recite a second DNA sequence encoding a foreign gene which anticipates this element of the present claims. Therefore, the claims of the ‘820 Patent fall entirely within the scope of the present claims. Moreover, the claims of the ‘820 Patent recite that the papovavirus is a BK papovavirus and also disclose inducible promoters and promoters under hormonal control which are recited by the present claims as well. Claims 1, 2, 4, 6, 8, 10, 15, 49, 54, 56, 58, 60, 65, 90, 94, 96, 98, 100, 105 and 199 recite kits and mammalian cells for use with the method of claims 113, 118, 120, 122, 124, 129, 154, 158, 160, 162, 164, 169 and 200 and which would have been inherent to the method of the claims of the ‘820 Patent and thus obvious to one of ordinary skill in the art.

Allowable Subject Matter

Claims 5, 7, 11-14, 16-46, 50-53, 55, 57, 59, 61-64, 66-89, 91-93, 95, 97, 101-104, 106-112, 114-117, 121, 125-128, 130-153, 155, 156, 159 and 165-198 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

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Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Konstantina Katcheves whose telephone number is (571) 272-0768. The examiner can normally be reached on Monday, Tuesday, Thursday and Friday 7:30 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Remy Yucel, Ph.D. can be reached on (571) 272-0781. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Konstantina Katcheves
20 February 2004



**JAMES KETTER
PRIMARY EXAMINER**

Continuation of Disposition of Claims: Claims rejected are 1-4,6,8-10,15,47-49,54,56,58,60,65,90,94,96,98-100,105,113,118,120,122-124,129,154,157,158,160-164,169, 199 and 200.

Continuation of Disposition of Claims: Claims objected to are 5,7,11-14,16-46,50-53,55,57,59,61-64,66-89,91-93,95,97,101-104,106-112,114-117,121,125-128,130-153,155,156,159 and 165-198.